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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/754,444	01/09/2004	Roger A. Stern	021827-000400US	7988

21971 7590 12/12/2005

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650 PAGE MILL ROAD
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EXAMINER

TOY, ALEX B

ART UNIT	PAPER NUMBER
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3739

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/754,444	Applicant(s) STERN ET AL.	
	Examiner Alex B. Toy	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 15-27 and 34-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 and 29-33 is/are rejected.
- 7) ☒ Claim(s) 14 and 28 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 June 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/26/04; 2/3/05</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS: 6/8/05</u> |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Invention I in the reply filed on November 15, 2005 is acknowledged. Claims 34-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Applicant's election with traverse of Species XIII in the reply filed on November 15, 2005 is acknowledged. The traversal is on the ground(s) that the application does not contain claims directed to Species III and IV. In view of the amended claims, the examiner concurs that there are no claims drawn to Species III and IV. Claims 15-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim.

In summary, claims 15-27 and 34-46 are withdrawn from further consideration. Claims 1-14 and 28-33 are examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 3739

Claims 1-3, 7-8, 10-11, and 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards (U.S. Pat. No. 6,006,755).

Regarding claim 1, Edwards discloses an electrode deployment apparatus for treatment of tissue in a body lumen, the apparatus comprising:

a plurality of electrodes 90 arranged on a surface of a dimensionally stable support 44 at a pre-selected electrode density (Fig. 5B); and

an expansion member 55 coupled to the support to deploy and selectively expose a portion 95 of the electrode surface while shielding a remaining portion 94 and maintaining the electrode density (col. 8, ln. 16-18 and Figs. 5B and 13).

Regarding claim 2, Edwards discloses the apparatus as in claim 1, further comprising wiring adapted to connect the electrodes to a radiofrequency power source as a multiplicity of bipolar pairs (col. 9, ln. 45-55).

Regarding claim 3, Edwards discloses the apparatus as in claims 1 and 2, wherein the support 44 comprises a non-distensible, electrode backing 61 (Fig. 5B).

Regarding claim 7, Edwards discloses the apparatus as in claim 1, wherein the electrodes are linear and arranged in a parallel pattern on the support (col. 11, ln. 45-59 and Figs. 5B and 18D).

Regarding claim 8, Edwards discloses the apparatus as in claim 1, wherein the electrodes are non-linear and arranged in a parallel pattern on the support (col. 11, ln. 45-59 and Figs. 5B and 18C).

Art Unit: 3739

Regarding claim 10, Edwards discloses the apparatus as in any one of claims 1 to 9, wherein the expansion member comprises an inflatable balloon 55 (col. 8, ln. 16-18 and Fig. 5B).

Regarding claim 11, Edwards discloses the apparatus as in claims 1 and 10, wherein the inflatable balloon inflates elastically (col. 8, ln. 16-19 and Fig. 5B).

Regarding claim 29, Edwards discloses the apparatus as in claim 1, further comprising a transesophageal catheter, wherein the expansion member is disposed at a distal end of the catheter (col. 3, ln. 35-37 and Fig. 5B).

Regarding claim 30, Edwards discloses a system for treating tissue, said system comprising the apparatus as in claims 1 and 29, and further comprising a RF power source coupled to the plurality of electrodes (col. 9, ln. 45-55).

Regarding claim 31, Edwards discloses an apparatus as in claims 1, 29, and 30, further comprising a multiplexer 25 coupled to the plurality of electrodes (col. 7, ln. 50-65 and Figs. 4B and 31).

Regarding claim 32, Edwards discloses an apparatus as in claims 1 and 29, further comprising a control device 34 coupled to the plurality of electrodes, the control device providing controlled positioning of the expandable member (col. 7, ln. 1-5 and Fig. 3).

Art Unit: 3739

Regarding claim 33, Edwards discloses an apparatus as in claims 1, 29, and 30, further comprising a temperature sensor coupled to the plurality of electrodes (col. 14, ln. 41-44 and Fig. 29).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards ('755).

Regarding claim 9, Edwards discloses the apparatus as in claim 1. The claim differs in calling for the parallel electrodes to have a width in the range from 0.1 mm to 3 mm and a spacing in the range from 0.1 mm to 3 mm (col. 11, ln. 45-59). Applicant has not disclosed any criticality or unexpected result associated

Art Unit: 3739

with these dimensions. Since the electrodes of Edwards can be placed in any desirable arrangement and the device of Edwards is also intended to treat the esophagus, it would require only routine skill in the art to modify the electrodes of Edwards to have the claimed dimensions.

Claims 1-13, 29-30, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux (U.S. Pat. No. 6,964,661 B2) in view of Wang (U.S. Pat. No. 5,462,545)

Regarding claim 1, Rioux discloses an electrode deployment apparatus for treatment of tissue in a body lumen, the apparatus comprising:

an electrode 128 arranged on a surface of a dimensionally stable support 136 (col. 5, ln. 61-63 and Figs. 1 and 3); and

Rioux discloses that a plurality of electrodes can be used in the invention (col. 2, ln. 42-45) but does not disclose their arrangement. Wang, however, teaches a plurality of electrodes 80 arranged on a surface of a dimensionally stable support at a pre-selected electrode density (Fig. 3D). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have arranged the plurality of electrodes of Rioux on the surface of the dimensionally stable support 136 at a pre-selected electrode density in view of the teaching of Wang as an obvious way of arranging a plurality of electrodes that is known in the art.

Rioux further discloses a self-expanding support to deploy and selectively expose a portion of the electrode surface while shielding a remaining portion and

Art Unit: 3739

maintaining the electrode density (col. 6, ln. 15-29, col. 7, ln. 43-45, and Figs. 2 and 3). The claim differs from Rioux in calling for an expansion member to expand the support instead of a self-expanding support. Rioux, however, discloses another embodiment, wherein ablation is achieved with a pair of expandable electrode arms. These arms can be self-expanding (col. 9, ln. 19-28 and Figs. 13 and 14) or balloon-expanded (col. 16, ln. 5-22, col. 17, ln. 14-23, and Figs. 11 and 12). Therefore, by analogy, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the self-expanding support of Figs. 2 and 3 to have been a balloon-expanded support in view the teaching from the alternate embodiments of Rioux as an obvious alternate method of expanding the support that is known in the art.

Regarding claim 2, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, Rioux discloses the apparatus further comprising wiring adapted to connect the electrodes of Rioux in view of Wang to a radiofrequency power source as a multiplicity of bipolar pairs (col. 3, ln. 3-11).

Regarding claim 3, Rioux discloses the apparatus as in claims 1 and 2 in view of Wang. In addition, Rioux discloses the apparatus, wherein the support 136 comprises a non-distensible, electrode backing (Figs. 1-3).

Regarding claim 4, Rioux discloses the apparatus as in claims 1-3 in view of Wang. In addition, Rioux discloses the apparatus, wherein at least a portion of the electrode backing is spirally furled about an expansion member prior to deployment (see the rejection of claim 1 and Fig. 3).

Regarding claim 5, Rioux discloses the apparatus as in claims 1-4 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes are aligned in a generally axial direction on the surface of the electrode backing (Fig. 3D).

Regarding claim 6, Rioux discloses the apparatus as in claims 1-4 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes are aligned in a generally transverse direction on the surface of the electrode backing (Fig. 3D).

Regarding claim 7, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes are linear and arranged in a parallel pattern on the support (Fig. 3A).

Regarding claim 8, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes are non-linear and arranged in a parallel pattern on the support (Fig. 3D).

Regarding claim 9, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, Wang discloses an apparatus, wherein the electrodes have a width in the range from 0.1 mm to 3 mm and a spacing in the range from 0.1 mm to 3 mm. Wang discloses that the electrodes are capable of any desired shape and arrangement (col. 8, ln. 15-20). Since applicant has not disclosed any criticality or unexpected result associated with these dimensions, it would require only routine skill in the art to modify the electrodes of Rioux in view of Wang to have the claimed dimensions.

Regarding claim 10, Rioux discloses the apparatus as in any one of claims 1 to 9 in view of Wang, wherein the expansion member comprises an inflatable balloon (see the rejection of claim 1).

Regarding claim 11, Rioux discloses the apparatus as in claims 1 and 10 in view of Wang, wherein the inflatable balloon inflates elastically (see the rejection of claim 1).

Regarding claim 12, Rioux discloses the apparatus as in claims 1 and 10 in view of Wang. In addition, Rioux discloses the apparatus, wherein the support is furled at least partially around the balloon, so that the support unfurls as the balloon is inflated (see the rejection of claim 1 and Figs. 2-3).

Regarding claim 13, Rioux discloses the apparatus as in claims 1, 10, and 12 in view of Wang. In addition, Rioux discloses the apparatus, wherein the support is furled in an overlapping manner (Fig. 3).

Regarding claim 29, Rioux discloses the apparatus as in claim 1 in view of Wang. In addition, the catheter of Rioux is inherently capable of use as a transesophageal catheter, and the expansion member of Rioux in view of Wang is disposed at a distal end of the catheter.

Regarding claim 30, Rioux discloses a system for treating tissue, said system comprising the apparatus as in claims 1 and 29 in view of Wang. In addition, Rioux discloses the system further comprising a RF power source coupled to the plurality of electrodes of Rioux in view of Wang (col. 3, ln. 3-11).

Regarding claim 32, Rioux discloses an apparatus as in claims 1 and 29 in view of Wang. In addition, Rioux discloses a control device 108 coupled to the plurality of electrodes, the control device providing controlled positioning of the expandable member (col. 8, ln. 24-39 and Fig. 1).

Regarding claim 33, Rioux discloses an apparatus as in claims 1, 29, and 30 in view of Wang. In addition, Rioux discloses a temperature sensor 150 coupled to the plurality of electrodes (col. 12, ln. 13-35 and Fig. 1).

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rioux ('661) in view of Wang ('545) and further in view of Edwards ('755).

Regarding claim 31, Rioux discloses an apparatus as in claims 1, 29, and 30 in view of Wang. The claim differs from Rioux in view of Wang in calling for a multiplexer coupled to the plurality of electrodes. Edwards, however, teaches a multiplexer 25 coupled to a plurality of electrodes in order to reduce the number of electrical pathways required from the shaft lumen to the electrodes (col. 7, ln. 50-65 and Figs. 4B and 31). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included a multiplexer in the apparatus of Rioux in view of Wang further in view of the teaching of Edwards in order to reduce the number of electrical pathways required from the shaft lumen to the electrodes.

Art Unit: 3739

Allowable Subject Matter

Claims 14 and 28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

US 4740207 A	USPAT	Kreamer; Jeffry W.
US 4969890 A	USPAT	Sugita; Yoichi et al.
US 4998539 A	USPAT	Delsanti; Gerard L.
US 5010895 A	USPAT	Maurer; Donald D. et al.
US 5192297 A	USPAT	Hull; Vincent W.
US 5517989 A	USPAT	Frisbie; Jeffrey S. et al.
US 5716410 A	USPAT	Wang; Lixiao et al.
US 5836874 A	USPAT	Swanson; David K. et al.
US 6006755 A	USPAT	Edwards; Stuart D.
US 6016437 A	USPAT	Tu; Hosheng et al.
US 6096054 A	USPAT	Wyzgala; Mark et al.
US 6102908 A	USPAT	Tu; Lily Chen et al.
US 6123703 A	USPAT	Tu; Lily Chen et al.
US 6123718 A	USPAT	Tu; Lily Chen et al.
US 6162237 A	USPAT	Chan; Winston Kam Yew
US 6254598 B1	USPAT	Edwards; Stuart D et al.
US 6258118 B1	USPAT	Baum; Abraham et al.
US 20030158550 A1	US-PGPUB	Ganz, Robert A. et al.
US 6800083 B2	USPAT	Hiblar; Thomas J. et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

Art Unit: 3739

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AT *AT*
12/5/05

Michael Peffley
MICHAEL PEFFLEY
PRIMARY EXAMINER